

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

CRIMINAL ACTION NO. 14-10363-RGS

UNITED STATES OF AMERICA

v.

GREGORY CONIGLIARO and SHARON CARTER

MEMORANDUM AND ORDER ON DEFENDANTS' MOTIONS  
FOR JUDGMENTS OF ACQUITTAL

June 7, 2019

STEARNS, D.J.

Once a promising niche drug business, the now defunct New England Compounding Center (NECC) willfully deviated from pharmaceutical industry safety standards in a mad pursuit of profits. Scores died and hundreds were injured when three contaminated batches of injectable methylprednisolone acetate (MPA) triggered a national outbreak of fungal meningitis. In the third of the four federal jury trials that followed, defendants Gregory Conigliaro and Sharon Carter were convicted of conspiring to defraud the United States Food and Drug Administration (FDA) by frustrating its regulatory oversight of NECC, in violation of 18 U.S.C. § 371.

Both Conigliaro and Carter now move for a judgment of acquittal pursuant to Fed. R. Crim. P. 29, arguing, *inter alia*, that because the FDA's

regulatory authority over compounding pharmacies was not clearly established, their conspiracy convictions were legally impossible and violated basic norms of due process. As I agree that defendants' rights to fair notice and due process were violated, their motions will be allowed.

## FACTS AND OVERVIEW

On December 16, 2014, a federal grand jury handed up an indictment targeting fourteen former owners and employees of NECC. What the indictment lacks in precision it compensates for in length: 131 separate criminal counts involving differing combinations of defendants are spread over seventy-three pages. The unifying theory of the indictment is the allegation that NECC came to be operated as a continuing criminal enterprise as defined by the Racketeer Influenced and Corrupt Organizations Act (RICO), in violation of 18 U.S.C. § 1961. In support of the theory, the indictment sets out seventy-eight RICO predicate acts ranging from second-degree murder to mail fraud. Confusing matters further, under the RICO heading, the indictment sets out two distinct racketeering enterprises – one centered on twenty-five predicate acts of second-degree murder connected to the shipment of the three lots of fungal-contaminated MPA,<sup>1</sup> the other

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<sup>1</sup> Only Barry Cadden, NECC's President, head pharmacist, and part owner, and Glenn Chin, the supervising pharmacist in charge of one of the two "clean rooms," were alleged to have participated in the murder

more loosely centered on mail fraud and violations of the federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*<sup>2</sup> Bringing up the tail end of the indictment, the majority owners of NECC, Carla and Doug Conigliaro<sup>3</sup> (who were not involved in the day-to-day operations of NECC) were charged with criminal contempts of Bankruptcy Court orders freezing their assets,

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racketeering enterprise. Each was separately tried in 2017 before a jury, and after lengthy deliberations in both cases, were acquitted of the predicate acts of second-degree murder.

<sup>2</sup> Cadden and Chin were both convicted for their participation in the mail fraud enterprise, along with racketeering conspiracy and various substantive mail fraud and FDCA counts. They are currently serving prison sentences. Tried together with Carter and Conigliaro were Gene Svirskey, a pharmacist who worked in NECC's "clean rooms" (found guilty of mail fraud racketeering and racketeering conspiracy); Christopher Leary, a clean room pharmacist (acquitted of racketeering and racketeering conspiracy but convicted of three counts of mail fraud and three counts of introducing adulterated drugs into interstate commerce); and Alla Stepanets, a pharmacist who also worked as a shipping clerk at NECC (acquitted of racketeering and conspiracy but convicted on six misdemeanor counts of violating the FDCA). Each has been sentenced. Another pharmacist, Joseph Evanosky, was acquitted on all counts. Scott Connolly, a pharmacy technician employed by NECC (at a time when he was unlicensed), pled guilty to ten counts of mail fraud in exchange for the dismissal of racketeering and racketeering conspiracy charges. Robert Ronzio, NECC's National Sales Manager, entered a cooperation agreement with the government and pled guilty to the conspiracy count at issue here.

<sup>3</sup> Doug Conigliaro is defendant Greg Conigliaro's brother. I will use the name Conigliaro to refer throughout this decision to Greg Conigliaro.

and with the illegal structuring of certain cash transactions involving their personal bank accounts.<sup>4</sup>

The indictment charged three distinct conspiracies: a racketeering conspiracy (Count 2),<sup>5</sup> a conspiracy to illicitly structure bank transactions (Count 128), and finally – and most relevant here – a *Klein* conspiracy to defraud (mislead) the United States, specifically the FDA, in violation of 18 U.S.C. § 371 (Count 3).<sup>6</sup> The odyssey of Count 3 is worth recounting, if in brief. In addition to Carter, Conigliaro, and Ronzio,<sup>7</sup> Cadden and Stepanets were also named as *Klein* conspirators and were acquitted by their respective

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<sup>4</sup> The court dismissed the contempt charges, and the Conigliaros pled guilty to the structuring offenses.

<sup>5</sup> Count 2 limned a racketeering conspiracy centered on the misrepresentations underlying the mail fraud allegations, in that the conspirators were alleged to have falsely represented to customers – the hospitals and clinics that purchased directly from NECC – that NECC’s drugs were fully compliant with United States Pharmacopeia (USP) standards 797 and 71, when in fact they were not, and that all of NECC’s compounding pharmacists and technicians were licensed by and in good standing with the Massachusetts Board of Pharmacy (MABOP), when one of the pharmacy technicians – Scott Connolly – was not.

<sup>6</sup> This species of conspiracy takes its name from *United States v. Klein*, 247 F.2d 908, 916 (2d Cir. 1957).

<sup>7</sup> Carter was acquitted of racketeering conspiracy, while Conigliaro was charged only with the *Klein* conspiracy.

juries; Ronzio, as previously noted, pled guilty pursuant to a cooperation agreement.<sup>8</sup>

The core allegation is that Conigliaro, Carter, and their fellow conspirators entered a corrupt agreement to defraud the FDA of its “right” to have its affairs conducted “free from corruption, fraud, improper and undue influence, dishonesty, unlawful impairment and obstruction.” Indictment, Dkt #1, ¶ 77. The generic conspiracy statute, 18 U.S.C. § 371, in broad terms criminalizes conspiracies “to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose.” The “defraud clause” of § 371 has been interpreted to encompass schemes that seek to “interfere with government functions.” *United States v. Goldberg*, 105 F.3d 770, 773 (1st Cir. 1997); *see also United States v. Barker Steel Co.*, 985 F.2d 1123, 1128 (1st Cir. 1993) (“The objective of the agreement is unlawful if it is for the purpose of impairing, obstructing or defeating the lawful function of any department of Government.”).

The government’s overarching theory was that the conspirators were engaged in a concerted effort to hold out NECC as a more or less conventional pharmacy regulated by the MABOP and Massachusetts law and regulations

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<sup>8</sup> Although Ronzio testified at the trial, he had very little to say about Carter and Conigliaro, neither of whom he knew nor dealt with on a regular basis.

which required that drugs be dispensed only on receipt of patient-specific and doctor-authorized prescriptions, when in actuality NECC was operating as a drug manufacturer producing compounded medications in bulk quantities without valid prescriptions. If so, according to the government's theory, NECC would have been "subject to heightened regulatory oversight by the FDA," Indictment ¶ 78, likely averting a tragedy like the 2012 fungal meningitis outbreak.

Implicit in the government's theory was the proposition that, as a matter of law (if not as a matter of real world practice), only two distinct entities crafted new drugs for the market: (1) the classic retail pharmacy (like Walgreens or CVS), where a neighborhood pharmacist received a doctor's patient-specific prescription and then compounded the prescribed ingredients to make the medication, and (2) industrial drug manufacturers (like Merck or Pfizer) that created drugs in bulk and shipped them wholesale to distributors. While state boards of pharmacy had supervisory jurisdiction over the former, manufacturers fell into the exclusive regulatory purview of the FDA.

The indictment alleged three material written misrepresentations by the alleged coconspirators to the FDA. The first, written in 2003 by Barry Cadden, responded to an FDA inquiry with the assertion that NECC was not

bound by the FDA’s code of good manufacturing practices “since we [NECC] are a compounding pharmacy, not a manufacturer.” Indictment ¶ 89. Similarly, in 2007, Cadden objected to any proposed FDA oversight, explaining that NECC “dispenses compounded medications [only] upon receipt of valid prescriptions.” *Id.* ¶ 91.<sup>9</sup> Finally, Conigliaro, in an October 1, 2004 letter to the FDA, described NECC as “a small-scale, family-run, compounding-only pharmacy, not a manufacturer.” *Id.* ¶ 90.<sup>10</sup> Although Carter was not alleged to have ever communicated directly with state or federal regulators, because of her position as NECC’s Director of Operations, she was presumed to have been aware that NECC was using celebrity or fictitious names<sup>11</sup> (or names of prior patients) as placeholders to facilitate the bulk shipment of compounded medications to hospitals and clinics.

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<sup>9</sup> Cadden was acquitted of the *Klein* conspiracy count at his trial; however, an acquittal of a coconspirator at an earlier trial has no preclusive significance for his alleged coconspirators at a later trial. *See, e.g., United States v. Espinosa-Cerpa*, 630 F.2d 328, 330-333 (5th Cir. 1980).

<sup>10</sup> While not dispositive, this single statement alleged against Conigliaro was made well outside the statute of limitations at a time that arguably preceded the onset of NECC’s transmutation into a high-volume compounder.

<sup>11</sup> Examples of obviously false patient names included “Wonder Woman,” “Flash Gordon,” and “Filet O’Fish.” *See United States v. Stepanets*, 879 F.3d 367, 370 n.3 (1st Cir. 2018).

Conigliaro, joined by the other defendants charged with the *Klein* conspiracy, first sought to have Count 3 dismissed under Rule 12(b)(3). *See* Mot. to Dismiss Count 3, Dkt ## 394, 395 (Nov. 13, 2015). He argued that Count 3 failed to allege a violation of § 371 as a matter of law, failed to give adequate notice of the nature of the offense, and that, as applied, § 371 was void for vagueness. The court denied the motion, finding that the grand jury had “more than adequately defined the purpose of the conspiracy: To induce regulatory authorities, including the FDA, into believing that NECC was doing business as a compounding pharmacy when in fact it was in the business of manufacturing drugs.” *See* Mem. and Order, Dkt # 671, at 5 (Sept. 21, 2016). Because a motion to dismiss an indictment is rarely, if ever, an appropriate vehicle to challenge the sufficiency of the underlying evidence, and because the indictment tracked the language of the statute and provided facts “specific enough to apprise the defendant of the nature of the accusation against him,” *United States v. Serino*, 835 F.2d 924, 929 (1st Cir. 1987), no more was required to allow the prosecution to proceed. *Cf. United States v. Stepanets*, 879 F.3d 370, 372 (1st Cir. 2018) (“[D]efinitely keep in mind that a court must deny a motion to dismiss if the motion relies on disputed facts.”).

Seven months later, after the verdict in the Cadden trial, Conigliaro (joined by Carter and Stepanets) filed a renewed Motion to Dismiss Count 3, see Dkt ## 1013, 1014 (Apr. 14, 2017). In the renewed motion, Conigliaro argued that the evidence offered and admitted at Cadden's trial "unequivocally establish[ed] that there [was] no discernible federal law defining any clear distinction between a compounding pharmacy and a drug manufacturer," and it was thus "legally impossible for the FDA to be defrauded in the manner the government alleged." Dkt # 1014, at 1-2. In its opposition to the motion, the government insisted that Conigliaro's "legal impossibility argument" was more accurately a factual one "that relies on evidence to be presented to and assessed by a jury at trial." See Gov't's Opp'n, Dkt # 1032 at 8 (May 12, 2017). The government further noted that it could "find no cases in the country, and indeed Conigliaro cites none, in which a court has dismissed a *Klein* conspiracy based on a theory of pure legal impossibility. This makes sense, since it is hard to imagine how conspiring to defraud the government could be legally impossible." *Id.* at 9.

In its order of October 10, 2017, see Dkt # 1232, the court noted that, despite the scholarly and judicial dissonance incited by the legal impossibility doctrine, in the consensus view, "pure" legal impossibility is recognized as an absolute defense. See, e.g., *United States v. Fernandez*, 722

F.3d 1, 31 (1st Cir. 2013). Although, as Conigliaro argued, many facts were not in dispute, without a fully developed record in the pending trial, the court concluded that it was unable to determine whether Conigliaro (and his fellow defendants) had successfully raised the defense in its pure (or perfect) form. *See Story Parchment Co. v. Paterson Parchment Paper Co.*, 282 U.S. 555, 566 (1931) (stating the general rule that where a “conclusion rested upon inferences from facts within the exclusive province of the jury,” such a conclusion may “not be drawn by the court . . . without usurping the functions of that fact-finding body”). Nor, as the court noted, would it have been fair to the government to rely solely on the evidence that the jury found insufficient to convict in Cadden’s case, as it was possible that “the government has some additional evidence of the FDA’s assessment of its legal position with respect to its ability to regulate compounding pharmacies like NECC that for some reason it chose to withhold in the Cadden trial.” *See* October 10, 2017 Mem. and Order, at 9 n.6.

At trial, Conigliaro renewed the motion to dismiss at the close of the government’s opening statement, *see* Dkt # 1686 (Oct. 15, 2018), and again after the government rested its case, *see* Dkt # 1779 (Dec. 3, 2018). After the jury returned a guilty verdict, Conigliaro and Carter filed the instant post-trial motions for acquittal with a supporting memorandum, *see* Dkt # 1819

(Dec. 19, 2018) and Dkt # 1853 (Jan. 25, 2019).<sup>12</sup> The court requested supplemental briefing on the issues of legal impossibility and due process and heard oral argument on February 26, 2019.<sup>13</sup>

## DISCUSSION

In analyzing a Rule 29 motion, the court views the evidence in the light most favorable to the verdict. *See, e.g., United States v. Santos-Soto*, 799 F.3d 49, 56-57 (1st Cir. 2015). A Rule 29 motion is granted sparingly and only where “the evidence, viewed in the light most favorable to the government, could not have persuaded any [reasonable] trier of fact of the defendant’s guilt beyond a reasonable doubt.” *United States v. Bristol-Mártir*, 570 F.3d 29, 38 (1st Cir. 2009). Pure issues of law seldom arise in

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<sup>12</sup> Both Carter and Conigliaro also seek, in the alternative, a new trial pursuant to Federal Rule of Criminal Procedure 33, alleging various prejudicial trial errors. Because the court will grant the motions for judgment of acquittal, it deems the requests for a new trial moot.

<sup>13</sup> With respect to defendants’ alternative argument that § 371 is void for vagueness as applied in violation of the Due Process Clause, as I noted in a previous order, “[l]ongstanding judicial interpretations of § 371 have made clear that the statute’s defraud clause constitutionally proscribes efforts to thwart the operation and purpose of a government program through deceit and trickery.” *See* Sept. 21, 2016 Mem. and Order, at 9 n.5 (citing various cases, including *Barker Steel*, 985 F.2d at 1131). However, to the extent that defendants’ void-for-vagueness challenge is predicated on principles of notice and fair warning, I will discuss these issues in the context of whether the alleged conspiracy was legally possible.

the context of a Rule 29 motion, which is usually directed to the sufficiency of the evidence. However, because the relevant test is whether the evidence “permits a rational jury to find each essential element of the crime charged beyond a reasonable doubt,” *United States v. Olbres*, 61 F.3d 967, 970 (1st Cir. 1995), it follows that the government’s failure to satisfy its burden of proof with respect to any element of the charged offense requires an acquittal. A judgment of acquittal is also required, notwithstanding the jury’s verdict, when the charged crime is a legal impossibility. See *Fernandez*, 722 F.3d at 31.

#### *A. Legal Impossibility*

The doctrine of legal impossibility as applied to inchoate crimes like attempt and conspiracy “has received much scholarly attention, but remains a murky area of the law.” *United States v. Hsu*, 155 F.3d 189, 199 (3d Cir. 1998); accord *Commonwealth v. Bell*, 67 Mass. App. Ct. 266, 266 (2006), *rev’d on other grounds*, 455 Mass. 408 (2009) (“If sheer volume of literature be the measure of fascination, then few subjects have been as intriguing for criminal law scholars as the nexus between the doctrine of impossibility and the crime of attempt.”). According to the author of an authoritative criminal law treatise, this fascination “is not surprising, for the question of whether we should punish a person who has attempted what was not possible under

the surrounding circumstances requires careful consideration of many of the fundamental notions concerning the theory and purposes of a system of substantive criminal law.” 2 LaFare, Substantive Criminal Law § 11.5(a), at 791 (6th ed. 2017).

The traditional solution to this conundrum is to draw a distinction between legal and factual impossibility, which seems easy enough, but is often difficult to apply in practice. Legal impossibility occurs “when the actions which the defendant performs or sets in motion, even if fully carried out as he desires, would not constitute a crime.”<sup>14</sup> *United States v. Oviedo*, 525 F.2d 881, 883 (5th Cir. 1976). Legal impossibility mirrors the more familiar principle of legality, under which no person is punishable by the state unless his conduct is in violation of a positive law; this is true even if he believes that he is committing a crime, and is doing his best to commit one.<sup>15</sup>

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<sup>14</sup> This statement of the doctrine is sometimes referred to as “pure legal impossibility” to distinguish it from so-called mixed fact/law impossibility. See generally Ira P. Robbins, *Attempting the Impossible: The Emerging Consensus*, 23 Harv. J. on Legis. 377, 390 (1986) (distinguishing among “pure” legal impossibility, mixed law/fact impossibility, and factual impossibility).

<sup>15</sup> Professor Gerhard Mueller has identified three essential components of the principle of legality:

1. *Nullum crimen sine lege*: there must be a valid criminal law completely covering the conduct of the defendant;
2. *Nullum crimen sine poena*: conduct cannot amount to a crime unless a punishment is provided; and

Examples of pure legal impossibility might include smoking marijuana in Massachusetts in the mistaken belief that the recreational use of marijuana was illegal in the Commonwealth, or shooting at a stuffed deer outside of deer hunting season, when in fact only real deer were protected and hunting was allowed year round, *see Hsu*, 155 F.3d at 199 n.16. Although cases like these are most often framed in the context of criminal attempts, “[o]bviously a charge of conspiracy to shoot a deer,” in the hypothetical suggested above, “would be equally untenable.” *In re Sealed Case*, 223 F.3d 775, 779 (D.C. Cir. 2000).

Factual impossibility, by contrast, arises when an attempt is frustrated by a physical circumstance of which the actor is unaware, the classical example being the attempt to pick an empty pocket. *See People v. Fiegelman*, 33 Cal. App. 2d 100 (1939). Other frequently cited examples of successfully prosecuted attempts in which factual impossibility furnished no defense include the solicitation of sex from a female police officer posing as an underage prostitute, *In Re Doe (S.D.)*, 855 A.2d 1100 (D.C. 2004); the sale

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3. *Nulla poena sine lege*: the act must be proscribed prior to its performance.

Mueller, *Criminal Theory: An Appraisal of Jerome Hall's Studies in Jurisprudence*, 34 Ind. L.J. 206, 217-218 (1959).

of a batch of fake methamphetamine touted as genuine to an undercover agent, *United States v. Sobrinski*, 127 F.3d 669 (8th Cir. 1997); an attempt to kill with a drink contaminated with what proved to be a subpotent poison, *Commonwealth v. Kennedy*, 170 Mass. 18, 22 (1897) (Holmes, J.), or with a gun that unbeknownst to the actor is unloaded, *State v. Damms*, 9 Wis.2d 183 (1960); and firing a deadly shot into a bed where the actor mistakenly believed the intended victim was sleeping, *State v. Mitchell*, 170 Mo. 633 (1902).

In cases of factual impossibility, “the defendant’s mental state was the same as that of a person guilty of the completed crime” and he is considered to be “deserving of conviction and is just as much in need of restraint and corrective treatment as the defendant who did not meet with the unanticipated events which barred successful completion of the crime.” 2 LaFave, *Substantive Criminal Law* § 11.5(a); *see also United States v. Dixon*, 449 F.3d 194, 202 (1st Cir. 2006) (“Recognizing that conduct falling short of a completed criminal objective still may pose a real threat to social order, we long have held that factual impossibility is not a defense to either liability or sentencing enhancements for inchoate offenses such as conspiracy or attempt.”).

In the case of legal impossibility, although a defendant might appear worthy of punishment – after all, his mind is infected with a criminal *mens rea* – the right of the state to impose punishment is constrained by the principle of legality, the boundaries of which are defined by considerations of due process, fundamental fairness, and just limits on the state’s deployment of the coercive instruments at its disposal. See Kadish et al., *Criminal Law and its Processes* 152 (9th ed. 2012) (“Perhaps most obvious [among the justifications for the legality principle] is the need to give individuals *fair warning* as to the conduct that could subject them to prosecution. Another is the need to *control discretion* of police, prosecutors, and juries. Reflecting these concerns, the legality principle bars both *retroactivity* and *vagueness*.”) (emphasis in original); *McBoyle v. United States*, 283 U.S. 25, 27 (1931) (Holmes, J.) (noting that fair warning should apprise people “in language that the common world will understand, of what the law intends to do if a certain line is passed”); see also *United States v. Lanier*, 520 U.S. 259, 266 (1997) (“[D]ue process bars courts from applying a novel construction of a criminal statute to conduct that neither the statute nor any prior judicial decision has fairly disclosed to be within its scope.”).<sup>16</sup>

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<sup>16</sup> “What then shall we say? That the law is sin? By no means! Yet if it had not been for the law, I would not have known sin. For I would not have

For these reasons, it is an axiomatic principle of the criminal law that wicked thoughts alone do not provide a basis for the infliction of punishment, no matter how distasteful or worthy of opprobrium the thoughts might be. *See Kennedy*, 170 Mass. at 21 (Holmes, J.) (noting that “the aim of the law is not to punish sins”). The doctrine of legal impossibility allows for a perfect defense in cases where suspect or even contemptible thoughts are unaccompanied by positive steps towards the achievement of an end that society has seen fit to criminalize. *See, e.g., Graham Hughes, One Further Footnote on Attempting the Impossible*, 42 N.Y.U. L. Rev. 1005, 1022 (1967) (“[A]n immoral motive to inflict some injury on one’s fellows coupled with a misapprehension about the content of the criminal law are not good reasons for conviction.”).

If to this point it all seems so clear, why the doctrinal confusion? As the Third Circuit has cogently explained, “the distinction between factual and legal impossibility is essentially a matter of semantics, for every case of legal impossibility can reasonably be characterized as a factual impossibility.” *United States v. Tykarsky*, 446 F.3d 458, 465-466 (3d Cir. 2006). For that reason, “most federal courts have repudiated the [factual-legal impossibility]

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known what it is to covet if the law had not said, ‘You shall not covet.’” Book of Romans 7:7.

distinction or have at least openly questioned its usefulness.” *United States v. Farner*, 251 F.3d 510, 512 (5th Cir. 2001) (collecting cases); *but see Fernandez*, 722 F.3d at 31 (recognizing the “pure” legal impossibility defense).

To elaborate, take the stuffed deer example: In 1953, a Missouri court concluded that a defendant could not be lawfully convicted of taking a deer out of season when his cervine trophy proved to be a taxidermical masterpiece for the simple reason that no law made the killing of a stuffed deer a crime. In reaching its decision, the Missouri court focused on the objective end-result of the defendant’s acts, rather than his *a priori* state of mind. *See State v. Guffey*, 262 S.W.2d 152 (Mo. App. 1953). Some years later, the Vermont Supreme Court on identical facts thought differently, fixing on the defendant’s “specific intent to take a wild deer out of season,” which was frustrated only by his mistake of an ersatz deer for an animate object. *See State v. Curtis*, 157 Vt. 629 (1991).

In the celebrated (by mavens of the law) case of *People v. Jaffe*, 185 N.Y. 497 (1906), the defendant attempted to purchase cloth that he (rightly) believed to have been stolen from its original owner. But unbeknownst to Jaffe, the cloth had been recovered, and the rightful owner had agreed to allow police to use the goods to set a trap for Jaffe. The New York Court of

Appeals vacated Jaffe's conviction, holding that once the goods had lost their stolen character, any attempt to receive them was a legal impossibility. Most scholars would (rightly in my view) criticize the thinking behind the Court of Appeals's decision. Jaffe, after all, had done everything within his power to complete the crime and came up short only because of an intervening factual circumstance of which he was unaware. But no one can doubt that had Jaffe succeeded he would have committed a real crime, one so rooted in the common law<sup>17</sup> and the popular imagination that it had its own nineteenth-century avatar in Dickens's fictional character Fagin, *Oliver Twist's* criminal overlord.

Being of the same mind, the authors of the Model Penal Code (MPC) repudiated *Jaffe* in all but name and advocated the abolition of factual impossibility as a defense. See ALI MPC § 5.01(1)(a) (1960) (an actor is guilty of attempt where he "purposely engages in conduct which would constitute the crime if the attendant physical circumstances were as he believes them to be."). The *Jaffe* approach, the draftsmen concluded:

is unsound in that it seeks to evaluate a mental attitude – "intent" or "purpose" – not by looking to the actor's mental frame of reference, but to a situation wholly at variance with the actor's beliefs. In so doing, the courts exonerate defendants in situations where attempt liability most certainly should be

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<sup>17</sup> See Note, *Receiving the Proceeds of Stolen Goods as a Criminal Offense*, 19 Colum. L. Rev. 229-233 (1919).

imposed. In all of these cases the actor's criminal purpose has been clearly demonstrated; he went as far as he could in implementing that purpose; and, as a result, his "dangerousness" is plainly manifested.

MPC § 5.01, Comment at 308-309 (1985). Although many state (and some federal) courts have followed the MPC's teachings, the Code does not question the legality principle, which remains well-embedded in the law. See Kadish et al., *Criminal Law and its Processes* 646 (9th ed. 2012) (noting that despite the competing approaches to legal impossibility, "[a]ll courts [have] agreed that there [is] a defense of legal impossibility when, unknown to the actor, what the actor planned to do ha[s] not been made criminal").

*B. Key Principles and the Peculiar Nature of the Regulatory Context*

Several modern cases illustrate facets of the impossibility defense in a way that is helpful to the resolution of this case. First, there is the classic instance of legal impossibility where there is no statute criminalizing the end-result envisioned by the actor. See *Hsu*, 155 F.3d at 199 n.16 ("For example, a hunter cannot be convicted of attempting to shoot deer if the law does not prohibit shooting deer in the first place."). The First Circuit has embraced the pure form of legal impossibility in several cases. An illustrative example is *United States v. Fernandez*, 722 F.3d 1 (1st Cir. 2013). In that case, the defendants were charged with violating the Travel Act, 18 U.S.C. § 1952, which as its name implies, prohibits interstate travel for purposes of

committing a crime. While there was no doubt about the travel or the defendants' nefarious intent, the crime that the defendants had in mind, the bribery of a Puerto Rican public official, had been fortuitously annulled by the legislature two weeks before the defendants' scheduled travel. On appeal, the First Circuit vacated the defendants' convictions. While in the eyes of the Court there was no doubt that the defendants sincerely believed that what they set out to do was criminal (bribing a public official), they had unknowingly "conspire[d] to do something that [was not] prohibited by these Puerto Rico bribery laws on the date they planned to do it." *Id.* at 32.

Second, the Courts of Appeals have not drawn a distinction between cases where there is no statute prohibiting a defendant's conduct and those where the prosecution fails to meet its burden of demonstrating that the goal of the alleged conspiracy violated some identifiable legal prohibition. Take, as an example, *United States v. Pierce*, 224 F.3d 158 (2d Cir. 2000). In *Pierce*, the government argued that the defendants – who were transporting large quantities of alcohol across the St. Lawrence River into Canada through a Mohawk Indian Reservation that spanned the border – were defrauding the Canadian government by evading that country's import duties and taxes. The Second Circuit reversed defendants' convictions because the

government, somewhat unaccountably, failed to introduce evidence at trial that Canada, in fact, taxed the import of alcohol. As the Court noted,

[t]he Pierces were accused of ‘wronging’ the Canadian government, by tricking or deceiving it, not to obtain money from it, but to deprive it of its right to collect money in tax and duty revenue . . . . To prove the existence of a scheme to defraud the Canadian government the prosecution had to prove the existence of such a right.

*Id.* at 165 (internal citations omitted).

*Pierce* is a modern analog to one of the most apocryphal hypotheticals in the world of legal impossibility, namely the case of Lady Eldon’s French Lace, presented by Dr. Wharton as follows:

Lady Eldon, when traveling with her husband on the Continent, bought what she supposed to be a quantity of French lace, which she hid, concealing it from Lord Eldon in one of the pockets of the coach. The package was brought to light by a customs officer at Dover. The lace turned out to be an English manufactured article, of little value, and of course, not subject to duty. Lady Eldon had bought it at a price vastly above its value, believing it to be genuine, intending to smuggle it into England.

Wharton, 1 Criminal Law 304 n.9 (12th ed. 1932).

Lady Eldon’s mental state and whether she could be convicted of an attempt has fascinated generations of legal scholars. However, the crucial distinction between Lady Eldon and *Pierce* is that in most iterations of the hypothetical, the existence of British customs duties on French lace is never questioned. The focus instead is on the relationship between Lady Eldon’s

*mens rea* (knowingly or purposefully trying to violate a law) and the fact, unbeknownst to her, that she had been cheated and was attempting to conceal from customs inspectors a shoddy substitute for genuine French lace. In a real case of *Regina v. Eldon*, the prosecutor would have had little difficulty meeting his burden of showing that Lady Eldon had attempted to violate an existing positive law.

Third, the case law establishes that legal impossibility is a defense to a § 371 *Klein* conspiracy where the federal government or one of its constituent agencies is not the intended victim of the planned fraud. In *Tanner v. United States*, 483 U.S. 107 (1987), the defendants were alleged to have conspired “to defraud the United States by impeding, impairing, obstructing and defeating the lawful functions of the Rural Electrification Administration (REA) in its administration and enforcement of its guaranteed loan program.” *Id.* at 128-129, quoting the indictment.

However, the actual target of the *Tanner* conspirators was a private contractor, Seminole Electric Company, that had received some financial assistance from the federal government in the form of a loan guaranteed by the Rural Electrification Administration (REA), a credit agency of the Department of Agriculture. The loan was intended to help fund the construction of a coal-fired power plant, but during the course of the

construction, the defendant had allegedly exploited his personal relationship with Seminole Electric's procurement manager to win the award of a subcontract to build some adjacent roads to the power plant in exchange for kickbacks.

The government argued that “because Seminole received financial assistance and some supervision from the United States, a conspiracy to defraud *Seminole* was *itself* a conspiracy ‘to defraud the United States.’” *Id.* at 130 (emphasis in original). The Supreme Court, through Justice O'Connor, disagreed, holding that “[t]he conspiracies criminalized by § 371 are defined not only by the nature of the injury intended by the conspiracy, and the method used to effectuate the conspiracy, but also – and most importantly – by the target of the conspiracy.” *Id.* The Court further noted that, even assuming that some portions of the legislative history of § 371 suggested it was intended to reach remote actors (like Seminole Electric) “performing functions on behalf of the Federal Government,” *id.*, – a proposition the Court thought doubtful – “the Government has presented us with nothing to overcome our rule that ‘ambiguity concerning the ambit of criminal statutes should be resolved in favor of lenity.’” *Id.* at 131, quoting *Rewis v. United States*, 401 U.S. 808, 812 (1971). It stands to reason that the same analysis would apply where the victim of the alleged fraud is a state

government, rather than a private entity, or one of its affiliated agencies (like a Board of Pharmacy).

A useful counterpoint to *Tanner* is Judge Woodlock's opinion in *United States v. Morosco*, 67 F. Supp. 3d 483 (D. Mass. 2014). In *Morosco*, the defendant was charged with manipulating the evaluations of public housing units in Chelsea, Massachusetts, that were subsidized by the United States Department of Housing and Urban Development (HUD). The defendants argued that because tinkering with HUD evaluations is nowhere identified in the federal criminal code as a crime, they could not lawfully have been convicted of defrauding HUD. Judge Woodlock rejected the argument, noting that "[t]he defraud clause of the conspiracy statute does not require the commission of a specific offense or the commission of any crime other than the conspiracy itself," *id.* at 488, a ruling later affirmed by the First Circuit, *see United States v. Morosco*, 822 F.3d 1, 6-7 (1st Cir. 2016).

What is crucial in Judge Woodlock's decision is any absence of doubt that the Chelsea Housing Authority (CHA) was subject to federal regulatory oversight. In addition to the monitoring of its expenditures of federal funds, the CHA was obligated to comply with HUD public housing regulations, which were intended to ensure safe and sanitary conditions for the inhabitants, and were enforced by regular inspections and compliance

evaluations. The housing evaluations that the defendants were accused of fraudulently manipulating were themselves conditions of the CHA's continued receipt of HUD funds.

The government advances several arguments for why a legal impossibility defense should not be recognized in this case, the most extreme of which is the proposition that “as a legal matter, the defense of legal impossibility does not apply to conspiring to defraud the United States.” Gov’t’s Conigliaro Opp’n, Dkt # 1884, at 12. In this regard, the government points to Judge Woodlock’s *Morosco* decision, suggesting that he “faced the precise issue of whether legal impossibility applies to the defraud clause of § 371.” *Id.* at 8. I am not sure where this idea comes from. *Morosco* does say that an illegal end (a conspiracy to defraud the United States) can be achieved through means that in isolation would not constitute independent crimes; it does not, however, hold that legal impossibility can never be a defense to a § 371 indictment.

A more solid argument advanced by the government is that “legal impossibility is not a defense to conspiring to interfere with the lawful functions of the government,” Gov’t. Mem. at 8, but this simply is another way of saying that legal impossibility is not a defense when the object of the conspiratorial agreement is to commit a crime. This circular formulation,

begs the question of what exactly are the “lawful functions of government” that are being violated. An arsonist who sets fires in a state forest and then with the help of a friend provides false information to state park rangers in an effort to obstruct the ensuing investigation would be entitled to raise a legal impossibility defense if he were charged under § 371 with defrauding the National Park Service. Similarly, fishermen plying a landlocked lake, subject to state regulatory requirements, who ignore catch quotas and restrictions, could raise a legal impossibility defense if charged with defrauding the NOAA National Marine Fisheries Service.

In these examples, it would make no difference how deviously the defendants behaved or how successful they were in “deceiv[ing] the [federal agencies] into thinking one thing . . . when another thing was in fact true,” as the government argues Conigliaro and Carter did here, see Gov’t’s Carter Opp’n, Dkt # 1885, at 16: if the National Park Service did not have regulatory authority over state forests, or if NOAA did not regulate fishing on freshwater lakes, these agencies would have had no official functions to be interfered with and a § 371 conspiracy charge would be a legal nullity.

Likewise, if the FDA, even if mistakenly, disavowed a legal right to regulate compounding pharmacies like NECC, and if the evidence at trial showed that the FDA abstained from regulating NECC as a result of its

internal determination of its own jurisdiction, a legal impossibility defense would plainly be available. This is not to fault the FDA: I recognize, as I will explain in greater detail, that the dividing line between pharmaceutical compounding and drug manufacturing had (prior to the NECC disaster) never been drawn with any clarity by Congress, which largely explains the confusion among state and federal regulators as to who was responsible for what. That, in turn, created a regulatory lacuna in the borderland in which NECC progressively came to operate. I described the hypotheticals above only to illustrate what I find to be a crucial point: while a defendant may be convicted of interfering with the lawful functions of a federal government agency even where his conduct taken in isolation would be lawful, and further, while it is not a requirement of conspiracy that the conspirators actually succeed in achieving their goal, *cf. United States v. Jimenez Recio*, 537 U.S. 270, 274 (2003), the government must still show here that some regulatory or investigative function of the FDA was compromised by the conspirators' actions.

This latter point was effectively driven home by counsel for defendant Sharon Carter at oral argument, to wit, another way to frame a legal impossibility defense to a *Klein* conspiracy is on the proposition that the government failed to meet its burden of proof on a required element of the

crime – namely, that the “government functions” with which the conspirators sought to interfere were in fact being exercised by the FDA. While I am unaware of any precedential case in which such a defense has proven effective, I can think of no reason why, on facts like those here, it could not succeed. This conclusion is influenced by basic principles of lenity and due process. *Cf. Lanier*, 520 U.S. at 267 (noting that the vagueness doctrine, the canon of strict construction of criminal statutes – that is, the rule of lenity – as well as fundamental notions of due process all require that it be “reasonably clear at the relevant time that the defendant’s conduct was criminal”). Whether the defense should succeed, however, requires an examination of the regulatory framework that governed compounding pharmacies during the life of the alleged conspiracy.

*C. The Evidence in this Case on the Scope of the FDA’s Authority*

As recounted by the Supreme Court in *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002), the FDA’s involvement with the drug compounding industry began with the passage of the FDCA in 1938. Section 505(a) of the FDCA provided that “[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed [with the FDA] is effective with respect to such drug.” “New drug” was defined as “[a]ny drug . . . not generally recognized, among

experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof.” *Id.* § 321(p). As written, the Act appeared to adopt a bright-line permitting scheme: any “new” drug had to secure FDA approval before it could be introduced into interstate commerce.

In practice, things did not prove so simple. As noted by the Supreme Court, “[f]or approximately the first 50 years after the enactment of the FDCA, the FDA generally left regulation of compounding to the States.” *Western States*, 535 U.S. at 362. Even though compounded drugs would often appear to fit within the FDA’s definition of a “new” drug, a work-sharing agreement was struck under which the regulation of so-called “traditional pharmacy compounding”<sup>18</sup> was left to state boards of pharmacies, while large-scale drug manufacturers were assigned to the exclusive purview of the FDA. As the FDA’s Dr. Janet Woodcock testified, “FDA has authority over all drugs in the United States; however, we didn’t have any specific regulatory scheme for this traditional pharmacy

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<sup>18</sup> See, e.g., *Professionals and Patients for Customized Care v. Shalala*, 56 F.3d 592, 593 (5th Cir. 1995) (“Pharmacies have long engaged in the practice of traditional compounding, the process whereby a pharmacist combines ingredients pursuant to a physician’s prescription to create a medication for an individual patient . . .”).

compounding. That was under the practice of pharmacy and under the state boards of pharmacies.” See Trial Tr. Day 27 (Nov. 19, 2018) at 10.

In 1992, concerned that “some pharmacists were manufacturing and selling drugs under the guise of compounding, thereby avoiding the FDCA’s new drug requirements,” *Western States*, 535 U.S. at 363, the FDA issued a Compliance Policy Guide (CPG) to more clearly define its regulatory policy. The 1992 CPG, which was not legally binding, announced that the “FDA may, in the exercise of its enforcement discretion, initiate federal enforcement actions . . . when the scope and nature of a pharmacy’s activities raises the kinds of concerns normally associated with a manufacturer and . . . results in significant violations of the new drug, adulteration, or misbranding provisions of the Act.” *Id.* at 362, quoting the 1992 CPG. The 1992 CPG iterated the FDA’s historical position of discretionary abstention from the policing of prescription-based compounding pharmacies, as well as pharmacies that compounded drugs without prescriptions in “very limited quantities” for buyers with whom they could demonstrate an “established professional practitioner-patient-pharmacy relationship.” *Id.* at 363.

Congress responded to this evolving regulatory uncertainty by passing the Food and Drug Modernization Act of 1997 (FDAMA), 21 U.S.C. § 353a (often referred to as Section 503A), which codified aspects of the FDA’s 1992

CPG. In its relevant parts, the FDAMA created a safe harbor for compounded drugs, exempting them from the FDCA's "new drug" requirements provided that certain criteria were met, most pertinently, that they be compounded in response to a valid prescription or only in limited non-prescription quantities where an established relationship existed between the specific pharmacist, patient, and prescribing physician. 21 U.S.C. § 353a(a). Other provisions specified safety and quality standards for the ingredients of compounded drugs, *id.* §§ 353a(b)(1)(A)-(B), prohibited the production of what were essentially carbon copies of commercially available drug products, *id.* § 353a(b)(1)(D), and added a provision forbidding pharmacies from soliciting customers or "advertis[ing] or promot[ing] the compounding of any particular drug, class of drug, or type of drug," *id.* § 353a(c).

The FDAMA, however, proved the genesis of an entirely new problem. In *Western States*, the Supreme Court found that the FDAMA's solicitation and advertising prohibitions on drug compounders to be an unconstitutional restriction on commercial speech. The Supreme Court did not, however, take a position on whether the solicitation and speech restrictions were severable from the rest of the FDAMA. Because the Ninth Circuit had previously held that these provisions were not severable, and that the FDAMA in its entirety was thus unconstitutional, *see Western States Medical Center v. Shalala*,

238 F.3d 1090 (9th Cir. 2001), that ruling remained undisturbed by the Supreme Court's decision.

In the void created by the *Western States* decisions, the FDA issued a new CPG in 2002, noting that, as best its lawyers could determine, “all of [the FDAMA] is now invalid.” 2002 CPG (Tr. Ex. 918); *see also* Trial Tr. Day 25, at 67 (testimony of Samia Nasr). As one district court noted, the 2002 CPG essentially reembraced the FDA's 1992 guidance and “the FDAMA's effusive attitude towards traditional pharmacy compounding.” *United States v. Franck's Lab, Inc.*, 816 F. Supp. 2d 1209, 1226 (M.D. Fla. 2011). While not fully conceding that *Western States* had rendered compounded drugs exempt from the “new drug” requirements of the FDCA, the 2002 CPG emphasized that the FDA had chosen to focus its discretionary oversight on large-scale drug manufacturers, while leaving the regulation of the smaller compounding pharmacies to the states.<sup>19</sup>

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<sup>19</sup> It is not that the FDA was oblivious to the transformation underway in the drug compounding industry. As the 2002 CPG explained:

FDA believes that an increasing number of establishments with retail pharmacy licenses are engaged in manufacturing and distributing unapproved new drugs for human use in a manner that is clearly outside the bounds of traditional pharmacy practice and that violates the Act. Such establishments and their activities are the focus of this guidance. Some “pharmacies” that have sought to find shelter under and expand the scope of the exemptions applicable to traditional retail pharmacies have

Muddying the waters further, in 2008, the Fifth Circuit parted company with the Ninth Circuit on the issue of severability, concluding that the provisions of the FDAMA that had not been explicitly invalidated by the Supreme Court in *Western States* remained viable. See *Medical Center Pharmacy v. Mukasey*, 536 F.3d 383 (5th Cir. 2008). The circuit split meant that the statutory framework governing the compounding industry differed from one part of the country to another. As noted by Dr. Woodcock in her testimony before the United States Senate, “[a] look at FDA’s attempts to address compounding over the past 20 years shows numerous approaches that were derailed by constant challenges to the law. As a result, presently, it is unclear where in the country section 503A is in effect.” Hearing Before

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claimed that their manufacturing and distribution practices are only the regular course of the practice of pharmacy. Yet, the practices of many of these entities seem far more consistent with those of drug manufacturers and wholesalers than with those of retail pharmacies. For example, some firms receive and use large quantities of bulk drug substances to manufacture large quantities of unapproved drug products in advance of receiving a valid prescription for them. Moreover, some firms sell to physicians and patients with whom they have only a remote professional relationship. Pharmacies engaged in activities analogous to manufacturing and distributing drugs for human use may be held to the same provisions of the Act as manufacturers.

Tr. Ex. 918 at 3.

the Senate Committee on Health, Education, Labor, and Pensions, S. Hrg. 113-756, May 9, 2013, at 11 (Trial Ex. 1033). Because Congress did not step in to address the muddled state of the law until 2013, after and in response to the NECC tragedy, depending on their geographical location, compounding pharmacies were either legally subject to the FDA's jurisdiction,<sup>20</sup> or were operating under the FDA's non-binding CPGs.<sup>21</sup>

The government draws a different conclusion from the legislative and judicial history that is straightforward in its simplicity.

[A]bsent the statutory safe harbor of FDAMA or the FDA's enforcement discretion outlined in the [2002] CPG, compounding pharmacies would be subject to the drug approval, manufacturing, and inspection provisions of the FDCA. Applying the legal framework to this case and Conigliaro's conviction, NECC was making new drugs, as defined in the FDCA, and was subject to the jurisdiction of the FDA. Thus,

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<sup>20</sup> FDA jurisdiction was, however, mostly a legal formality given the FDA's 2002 determination that the entire FDAMA was invalid.

<sup>21</sup> Intervening lower federal court decisions took note of the state of uncertainty. *See, e.g., Cruz v. Preferred Homecare*, 2014 WL 4699531, at \*3 (D. Nev. Sept. 22, 2014) (noting that, because the Ninth Circuit's ruling on non-severability remained in place following *Western States*, and because Congress did not pass a new statute until 2013, "between 2002 and November 2013, there was no federal statute in effect that expressly provided for the FDA to regulate compounding pharmacies"); *Franck's Lab*, 816 F. Supp. 2d at 1248 ("Though it certainly has the statutory authority to do so, the FDA has chosen not to draw the line between manufacturing and traditional compounding with formal regulations. Nor has it sought to distinguish traditional pharmacy compounding from pharmacists who are manufacturing under the guise of compounding.").

because NECC was (undisputedly) not following the FDCA's new drug requirements, the question of whether NECC was legally making drugs was whether NECC met the safe harbor factors outlined in FDAMA and the 2002 CPG, that is, compounding drugs in response to patient specific prescriptions. If it was not doing so, it was not legally making drugs.

See Gov't's Opp'n, at 7.

The difficulty with the government's position lies in the fact that, apart from the Supreme Court's intervention in *Western States*, the most significant actor rejected it: the FDA itself. In internal memoranda, testimony by senior FDA officials before various House and Senate committees as part of Congress's investigation into the fungal meningitis outbreak,<sup>22</sup> in court testimony and exhibits offered at the trial of this matter, the picture emerges of an agency struggling to make sense of a statutory regime that Congress had not updated since 1938 and that had been overwhelmed by the rapidity of the advances in modern medicine and pharma. Moreover, the FDA was under considerable pressure as a result of the restructuring of the drug industry itself. Over the years, for reasons of patent expirations and profits, traditional drug manufacturers had largely discontinued the production of a number of generics and specialty drugs, creating a demand vacuum that compounding pharmacies like NECC

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<sup>22</sup> The FDA testimony cited in this decision was played to the jury in videotaped form or read into the record at trial, unless otherwise noted.

stepped in to fill. The FDA recognized that an overly robust enforcement posture on its part towards compounders could jeopardize hospitals' and clinics' supplies of potentially life-saving medications.

The evidence at trial reinforced the notion that entities like NECC did not fit neatly into the compounding-manufacturing dichotomy that had historically influenced the FDA's enforcement strategy. Dr. Woodcock noted in her Senate testimony, the FDA had "long recognized . . . the value of pharmacy compounding and the way it can tailor medications to different unmet medical needs," but "this industry has changed and grown up, so this is a new type of practice that has evolved. And it raises the stakes on risk, because they're doing large-scale, sterile processing of drugs." Trial Ex. 1033 at 22. She also testified that while "presently, there are hundreds of other firms [besides NECC] operating as compounding pharmacies . . . the current legal framework does not provide FDA with the tools needed to identify and adequately regulate these pharmacies to prevent product contamination." Trial Tr. Day 27, at 73-74.

Because some states allowed anticipatory compounding – that is, the production of compounded drugs for use as office stock before hospitals and clinics could know the identities of the patients who would be served – the FDA was unable under Congressional questioning to articulate a clear line

between compounding and drug manufacturing. The following is culled from several exchanges involving then FDA Commissioner Margaret Hamburg, Dr. Woodcock, and members of Congress.

MR. BURGESS: You define manufacturers. Someone is making 30,000 vials of stuff a month, is that a manufacturer?

DR. WOODCOCK: Well, say, if I am Janet the pharmacist, all right, and I have a pharmacy that is licensed in a State, right, and I am compounding drugs, right, and then I decide, well, I want to broaden my activities, and my State allows the anticipatory compounding and my State allows office stock, right, so I can compound those in advance of or without a prescription and send them. And there is no —

MR. BURGESS: 30,000 vials a month?

DR. WOODCOCK: There is no — what is the number? That is the thing we have been struggling with for 12 years. Is it 10 vials? Is it 1,000 vials . . . . There is no volume limit in the statute.

Testimony Before the House Subcommittee on Oversight and Investigations,  
Committee on Energy and Commerce, May 23, 2013, at 28.

MRS. ELMERS: OK. Now let me ask this question. The number and how much a pharmacy is making seems to be the issue of where it falls, what jurisdiction. In your own words, where do you, where would you see that line of action? What do you see, how much product can a compounder make without being designated a manufacturer?

DR. WOODCOCK: That is what we have been struggling with since the 503 was passed, OK, there is no line in there in the statute. And so what is an inordinate quantity? We don't know. Is it 10 units? Is it 1,000 units? Is it 17,000 units? So we have endeavored to use other criteria to say, OK, when you would be subject to Federal jurisdiction.

*Id.* at 43-44.

MR. GREEN: What is the FDA's position on office-use compounding pursuant to State law where it occurs? Under the current federal law, FDCA, and under the legislation being considered in the Senate?

DR. WOODCOCK: Well, right now under current Federal law it is blurry, all right, as far as how much you could make. You all are saying to me that you think you can tell what a manufacturer is, but there is no bright line in the statute that says when you cross that line and become a manufacturer.

*Id.* at 37.

MS. CASTOR: I don't think that it is overly complex. I think there's a difference in outlook here on whether you have certain authority. And I think it's clear under the 1997 law and these court cases that compounders were exempted and are not manufacturers. So, we – the Congress, has a responsibility now to act and clarify it. And there's got to be additional oversight of the states. If the states – if they're going to drop the ball and they're not – they're going – they're not going to provide proper oversight, then it's time for the feds to step in and give FDA the tools it needs to prevent these tragedies from ever happening again.

DR. HAMBURG: I don't know if I'm allowed to make a comment, but I think, you know, that speaking to the complexity of the issue and the changing, evolving industry overlaid on top of a fragmented and ambiguous legal framework, it is important to understand that this notion of sort of black and white, compounder or manufacturer, you know, it just is trying to fit a square peg into a round hole.

Testimony Before the House of Representatives Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, Nov. 14, 2012, at 87.

As aptly summarized by Dr. Woodcock in her 2013 Senate testimony, “[t]he current legal framework is the wrong fit for this industry, which has evolved and grown tremendously over the past 12 years and really wouldn’t be recognizable to a traditional pharmacist of, say, 25 years ago.” Trial Ex. 1033 at 7. As a consequence, “FDA’s ability to take action against compounding that exceeds the bounds of traditional pharmacy compounding and poses risks to patients has been hampered by limitations and ambiguities in the law, which have led to legal challenges to FDA’s authority to inspect pharmacies and take appropriate enforcement actions.” *Id.* at 9. Internally, in response to the Middle District of Florida’s decision in the *Franck’s Lab* case, an FDA Memorandum titled “Rationale for 503A Policy and Regulatory Strategy” (Oct. 14, 2011) observed:

The recent District Court opinion regarding *United States vs. Franck’s Lab Inc.* recognized that “though [FDA] has the statutory authority to do so, the FDA has chosen not to draw the line between manufacturing and traditional compounding with formal regulations.” This lack of notice to industry of the regulatory distinction between compounding and manufacturing has created a difficult regulatory environment which has led to uncertainty in enforcement and has provided no clear guidance to the industry.

See Dkt # 1570-1, at 41 (Pretrial Evidentiary Stipulation).

The reservations expressed by the FDA, internally and in public, were not a product of timidity. The FDA had good reasons for its hesitancy beyond

the lack of clear statutory guidance from Congress. High-volume anticipatory compounding centers like NECC filled a void created by the many hospitals that had shuttered their in-house pharmacies for reasons of convenience (many of the more sophisticated drugs were difficult to produce in-house), or because of insurance costs and the fear of liability. Again, as noted by Dr. Woodcock, “hospitals have come to rely on compounding pharmacies that function as ‘outsourcers’ producing sterile drugs previously made by hospital in-house pharmacies.” Trial Ex. 1033, at 10. And, as previously observed, large-scale drug manufacturers were for similar reasons leaving the business of high-risk anticipatory drug compounding. See Trial Tr. Day 27, at 22-23 (Nov. 19, 2018) (testimony of Janet Woodcock) (“[A] need had grown up that didn’t exist before, and the major – the large manufacturers were not following that need, that void, for those outpatient clinics or in-and-out surgery and so forth.”).

Because the newer model compounding pharmacies were “supply[ing] large numbers of sterile drugs produced in relatively large quantities to hospitals nationwide,” the FDA legitimately feared that enforcing a requirement from a 1938 statute that compounders receive FDA approval for each new, compounded medication prior to its being shipped, would likely “cause disruptions in the supply of drugs to hospitals and other health care

providers.” Trial Ex. 1033; *see also* Trial Tr. Day 27 (Nov. 19, 2018), at 102 (“[W]e would have created . . . patient harm by suddenly cutting this off, by bringing it to a stop. And that’s why we were advocating, and much of the [congressional testimony] clips that were shown here [at trial] were in the context of us saying, No, we need a better framework.”); FDA Mem. of October 14, 2011, Dkt # 1570-1, at 41 (Pretrial Evidentiary Stipulation) (“The compounding industry is growing. Studies estimate that less than 1% of all prescriptions were compounded in the 1970s, and was expected to grow to 10% by 2010. Drug shortages of commercially available drug products are increasing and as a result the demand for similar compounding products has also risen.”).

These ambiguities extended to the FDA’s direct dealings with NECC itself. In pre-outbreak inspections of NECC, the FDA labeled the company as either a “pharmacy” or “compounding pharmacy,” but never as a drug manufacturer. The FDA also consistently took the position that regulatory jurisdiction over NECC fell to MABOP. For instance, when the Colorado Board of Pharmacy notified the FDA that NECC was shipping drugs in bulk quantities across state lines, *see* Trial Ex. GX 701, the FDA’s response was to refer the Colorado Board to its counterparts at MABOP.

This is not to place undeserved blame on the FDA for the NECC debacle. As Dr. Woodcock noted, in hindsight, the FDA “should have been more aggressive in applying our existing authorities to this industry, in spite of the ambiguous statute and multiple challenges by industry.” Trial Ex. 1033, at 7. But to have done so would have risked compromising the supply of much needed drugs to hospitals that had few other avenues for procuring them. Moreover, after the *Western States* decisions and what Dr. Hamburg described as the resulting “disconnect between different legal requirements in different parts of the country,” Testimony Before the House of Representatives Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, Nov. 14, 2012, adoption by the FDA of a nationally uniform enforcement policy with respect to compounding pharmacies would have been the legal equivalent of threading a needle without an eye. To summarize, the FDA’s “authority over compounding [was] limited, unclear, and contested,” *id.*, as the FDA had long recognized.<sup>23</sup>

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<sup>23</sup> As stated by Dr. Woodcock in her testimony at trial:

Q: You do know that there was lots of internal debates within the FDA about authority, though, right?

A: Yes.

Q: And those internal debates lasted years, didn’t they?

A: Yes.

The FDA admirably admitted in the aftermath of the outbreak that it could have done more, but it did not believe that Congress had given it the appropriate statutory tools to do so. Certain members of Congress were equally frank in retrospect about having dropped the ball. Trial Ex. 1033, at 18 (statement of Senator Warren) (“I just want to say I think it’s unconscionable that we have failed to regulate this industry for so long and put the public at risk.”); Testimony Before the House of Representatives Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, Nov. 14, 2012, at 87 (statement of Representative Castor) (“We – the Congress – has a responsibility now to act and clarify it . . . . If the states – if they’re going to drop the ball and they’re not . . . going to provide proper oversight, then it’s time for the feds to step in and give FDA the tools it needs to prevent these tragedies from ever happening again.”).

Be that as it may, whatever the efforts that were finally undertaken to fix federal law as applied to compounding, the evidence plainly shows that during the life of the charged conspiracy, the FDA was not, and did not believe that it should be, in the business of regulating companies like NECC

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Q: Decades?

A: Perhaps decades.

See Trial Tr. Day 27 at 52.

that were engaged in anticipatory pharmacy compounding. Thus, the bottom line: during the critical times, these defendants (and NECC) could not have defrauded the FDA by interfering with the relevant regulatory functions because there were none to speak of.

#### *D. The Government's Response*

The government does not contest that there was internal disagreement at FDA over whether (and how) to regulate entities like NECC. The government's response rather is an argument based on its reading of the FDCA: because NECC was making "new drugs" as defined by the statute, the failure of the FDA to exercise regulatory authority over NECC is immaterial to whether it *could have* done so. As the government phrases it, "[t]he lack of a statute or clear regulation by which the FDA defined compounding pharmacies and manufacturers is irrelevant to the fraud perpetrated by Conigliaro and his co-conspirators by lying to the FDA and the MABOP about NECC's true activities in order to try to conceal them." Gov't's Conigliaro Opp'n at 10.

This argument – that what the FDA thought and did was irrelevant – is typified by the following exchange between the government and Dr. Woodcock on direct examination at trial:

Q: Was there anything under federal law that allowed for drugs to be compounded and shipped without prescriptions?

A: No.

Q: So back in 2012, for purposes of federal law, were there only two categories in which a drug maker could fall into?

A: That's correct. There was compounding, and that was the individual prescription, and then there was drug manufacturing, which was everything else.

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Q: But for federal purposes, if you were compounding drugs without a prescription, you'd fall under that manufacturing one?

A: That's correct.

See Trial Tr. Day 27 at 16-18.

This may well be true, but the exchange illustrates the government's worrisome position that, in this context, what is not affirmatively permitted by the law is criminally prohibited. Is it really the case that a lawyer's parsing of the hypothetical jurisdiction that the FDA *might* have asserted over "new" drugs, based on a 1938 statute, standing alone – and irrespective of the contrary positions since taken by the FDA itself – an adequate basis for a § 371 conspiracy indictment? Ultimately, resting criminal liability on such a shaky foundation raises legitimate concerns of constitutional due process and fair notice. It is a fundamental principle that the criminal law should give reasonably clear direction to those it might otherwise ensnare as to how they can avoid criminal liability.

### *E. Due Process and Notice*

At least one district court has rejected the argument, albeit in the slightly different context of compounding animal drugs, that the statutory authority given to the FDA to regulate “new drugs” can be an adequate basis for liability even when the agency has taken the opposite view in its enforcement history and public pronouncements. As noted by Judge Corrigan, “[t]he FDA cannot simply upset the expectations it helped to create through decades of inaction without explanation, especially where its asserted expansion of authority impacts the federal-state balance and potentially subjects many individuals and companies to criminal liability. This conclusion is supported by both the plain statement rule and the rule of lenity.” *Franck’s Lab*, 816 F. Supp. 2d at 1253-1254 (footnote omitted).<sup>24</sup>

I find Judge Corrigan’s reasoning especially persuasive in this respect: because the FDA is the purported victim of the alleged *Klein* conspiracy, extending the FDA’s regulatory power to entities that it had not heretofore

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<sup>24</sup> The Eleventh Circuit ultimately vacated the decision in *Franck’s Lab*, pursuant to a joint motion of the parties to dismiss the appeal and vacate the district court’s ruling. See *United States v. Franck’s Lab*, 2012 WL 10234948 (11th Cir. Oct. 18, 2012). The court is not relying on *Franck’s Lab* for its precedential force (which would be limited in any event as an out-of-circuit district court opinion), but rather for its persuasive discussion of various points germane to this case, especially with respect to the relationship between the FDA’s prior enforcement history and the rule of lenity.

seen fit to regulate raises legitimate concerns of lenity and due process. In *McBoyle*, Justice Holmes wrote that “[a]lthough it is not likely that a criminal will carefully consider the text of the law before he murders or steals, it is reasonable that a fair warning should be given to the world in language that the common world will understand, of what the law intends to do if a certain line is passed.” 283 U.S. at 27. This sentiment has been iterated on numerous occasions by the Supreme Court and the First Circuit. *See, e.g., United States v. Harriss*, 347 U.S. 612, 617 (1954) (“The underlying principle is that no man shall be held criminally responsible for conduct which he could not reasonably understand to be proscribed.”); *United States v. Hussein*, 351 F.3d 9, 13 (1st Cir. 2003) (“The criminal law should not be a series of traps for the unwary. To that end, the Due Process Clause demands that criminal statutes describe each particular offense with sufficient definiteness to ‘give a person of ordinary intelligence fair notice that his contemplated conduct is forbidden.’”), quoting *Harriss*, 347 U.S. at 617.

As the Supreme Court explained in *Lanier*, the fair warning requirement has at least three constituent parts:

First, the vagueness doctrine bars enforcement of “a statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application.” . . . Second, as a sort of “junior version of the vagueness doctrine,” the canon of strict construction of criminal statutes, or rule of lenity, ensures

fair warning by so resolving ambiguity in a criminal statute as to apply it only to conduct clearly covered. Third, although clarity at the requisite level may be supplied by judicial gloss on an otherwise uncertain statute, due process bars courts from applying a novel construction of a criminal statute to conduct that neither the statute nor any prior judicial decision has fairly disclosed to be within its scope. In each of these guises, the touchstone is whether the statute, either standing alone or as construed, made it reasonably clear at the relevant time that the defendant's conduct was criminal.

520 U.S. at 1225 (internal quotations and citations omitted). Each of these principles is implicated here. Because the FDA did not believe it had the statutory authority to regulate these new forms of pharmacy compounders, people “of common intelligence” in the industry were left to guess as to the FDA’s future enforcement policies. Previous judicial decisions had not “fairly disclosed” to the industry that the FDA was poised to insert itself as a hands-on overseer of compounding pharmacies; to the contrary, the few cases that had been decided mostly pointed in the opposite direction. And finally, even if the argument could be made that the FDA had never affirmatively and publicly renounced its residual authority to regulate compounders, the contradictory nature of the public pronouncements it did make on the subject would justify application of the tie-breaking rule of lenity.

“[T]he touchstone of the rule of lenity is statutory ambiguity,” *Bifulco v. United States*, 447 U.S. 381, 387 (1980), and attempts to extend the rule

of lenity beyond the context of ambiguous criminal statutes have generally not fared well in the Courts of Appeals, *see, e.g., United States v. Gonzalez*, 407 F.3d 118, 124 (2d Cir. 2005) (joining a sister circuit “in holding that the rule of lenity is not applicable to a district court’s fact-finding role at sentencing”). Yet the basic principle that a criminal sanction must follow a clear and positive legal prohibition, so that defendants “are not punished for violating an unknowable something,” *Screws v. United States*, 325 U.S. 91, 105 (1945) – has been applied by the Supreme Court before in the context of determining the scope of an alleged *Klein* conspiracy, *see Tanner*, 483 U.S. at 131, and is simply too well-established and too important to ignore here. *See Raley v. State of Ohio*, 360 U.S. 423, 438 (1959) (“Inexplicably contradictory commands in statutes ordaining criminal penalties have, in the same fashion, judicially been denied the force of criminal sanctions.”); *United States v. Wilson*, 159 F.3d 280, 289 (7th Cir. 1998) (Posner, C.J., dissenting) (“The purpose of criminal laws is to bring about compliance with desired norms of behavior. . . . This purpose is ill served by keeping the law a secret . . . .”). This is all the truer when bad things have happened and the thirst for accountability is most acutely felt.

## CONCLUSION

For the foregoing reasons, the Motions of Sharon Carter and Gregory Conigliaro for Judgments of Acquittal are ALLOWED. The Clerk will enter the judgments accordingly and discharge the defendants.

SO ORDERED.

/s/ Richard G. Stearns

UNITED STATES DISTRICT JUDGE